UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, ABBOTT MOLECULAR INC., and ABBOTT LABORATORIES INC.,

Plaintiffs,

v.

DAKOCYTOMATION CALIFORNIA, INC.,

Defendant.

No. C 05-03955 MHP

MEMORANDUM & ORDER
Re: Motion for Preliminary Injunction

Plaintiffs The Regents of the University of California ("UC Regents"), Abbott Molecular Inc., and Abbott Laboratories Inc. (collectively, "Abbott") brought this patent infringement action against defendant DakoCytomation California, Inc. ("Dako"), alleging infringement of two United States patents related to *in situ* DNA hybridization. Now before the court is plaintiffs' motion for a preliminary injunction prohibiting defendant from manufacturing or selling its *HER2* FISH pharmDx™ kit ("Dako kit" or "accused kit") in the United States. Having considered the parties' arguments and submissions, and for the reasons set forth below, the court enters the following memorandum and order.

BACKGROUND[1]

I. The Parties

Both Dako and Abbott manufacture diagnostic kits which measure the frequency of a particular gene—the "HER2" gene—associated with an aggressive form of breast cancer. Declaration of Edward Michael in Support of Plaintiffs' Motion for Preliminary Injunction ("Michael Dec.") ¶ 15; Declaration of Dennis Chernoweth in Support of Defendant's Opposition to Plaintiffs' Motion for Preliminary Injunction ("Chernoweth Dec.") ¶ 10. Approximately 25 percent of breast cancer patients have additional copies of the HER2 gene in their cancerous cells. Chernoweth Dec. ¶¶ 5–6. The HER2 protein, which is encoded by the HER2 gene, makes the cancer cells resistant to traditional forms of cancer treatment. Michael Dec. ¶ 12. A drug called Herceptin is effective in mitigating the effects of the excess HER2 genes, but is expensive to administer. Id. ¶¶ 12, 14. The kits offered by Abbott and Dako identify the presence of excess HER2 genes in the cancerous cells, which assists in deciding if treatment with Herceptin is needed.

Abbott is the current market leader for "genomic" tests that directly detect excess copies of the HER2 gene. The Abbott PathVysion Test was administered to 42 percent of breast cancer patients in 2004. Michael Dec. ¶ 26. The accused Dako kit is not currently in widespread use in the United States. As of the filing date for Abbott's motion, Dako had sold only 25 kits to customers in North and South America, for a total of less than $50,000 in gross revenue. Chernoweth Dec. ¶¶ 18–19. Dako is, however, also the manufacturer of an older diagnostic kit that detects excess HER2 protein, rather than directly detecting excess copies of the HER2 gene. Id. ¶ 9. Dako's older kit currently remains the most commonly used initial test for determining the need for treatment with Herceptin. Id. ¶ 9. The older kit, however, fails to yield reliable results in 9 to 15 percent of its applications. Id. ¶ 10.

The parties disagree as to which company has greater power in the current market. Dako argues that Abbott is in a position of greater power, as a result of its overall size—many times larger than Dako—and the existing market for the PathVysion test. Abbott, in response, notes that Dako's sales force for HER2 kits in the United States is larger than Abbott's, and argues that Dako will be

able to make use of its existing base of customers for the older kit as leverage in promoting the accused kit.

II. The Asserted Patents

Abbott holds the two patents at issue in this lawsuit, U.S. Patent No. 5,447,841 (the "'841 patent") and U.S. Patent No. 6,596,479 (the "'479 patent"). The two asserted patents have identical specifications but were issued almost eight years apart and have different claims. Both patents relate generally to the identification of target genes in a tissue sample through DNA hybridization. In DNA hybridization, sections of nucleic acid that are labeled, usually with a fluorescent dye ("hybridization probes"), are bonded to complementary "target" regions of chromosomal DNA—such as the gene encoding the HER2 protein. See, e.g., '841 patent at cols. 2–3. The fluorescent label provides visual confirmation of the presence of the target gene. Id.

The basic technology involved in DNA hybridization predates the asserted patents. The inventions described in the asserted patents improve upon the prior art hybridization process by increasing its accuracy in two ways. First, in order to guarantee that a sufficient number of hybridization probes will bond to the target region, the claimed inventions use a "heterogeneous mixture of labeled unique sequence nucleic acid fragments" that "results in a substantially uniform distribution of fragments hybridized to the chromosomal DNA." Id. at 4:7–9.

Second, the claimed inventions include countermeasures that prevent hybridization probes from bonding to regions of the chromosomal DNA outside of the target region. Of particular concern are so-called "repeat" or "repetitive" sequences of DNA which occur throughout the chromosomes but do not actually encode proteins. When these repeat sequences are similar in structure to parts of the target regions, hybridization probes designed to attach to those parts of the target region may instead hybridize at many undesired locations. The invention of the '841 patent deals with repeat regions by using unlabeled hybridization probes ("blocking nucleic acid") to bond to the repeat sequences, which in turn prevents labeled probes from bonding to any repeat sequences in the chromosomal DNA. See '841 patent at 17:9–12 (claiming "blocking nucleic acid that comprises fragments which are substantially *complementary to repetitive segments in the labeled*

nucleic acid").[2] The invention of the '479 patent deals with repetitive sequences by employing labeled hybridization probes that are "unique"—not complementary to any repeat sequences. See '479 patent at 16:9–10 (claiming a "heterogeneous mixture of labeled *unique sequence* nucleic acid fragments") (emphasis added). These countermeasures constitute the key advances in the asserted patents.

III. The Accused Kit

DNA hybridization may be performed on genetic material residing in various forms of tissue. For example, hybridization can be performed on DNA located within whole cells. The cells may be processed prior to hybridization in order to permit the DNA probes to access the genetic material contained in the nucleus. See '841 patent at 11:24–12:2.

Dako's accused HER2 kit does not operate on whole cells. Instead, the accused kit operates on "histologic" samples of cancerous breast tissue that have been fixed using a chemical called formalin, and then thinly sliced for observation under a microscope. Declaration of Andreas Schønau in Support of Defendant's Opposition to Plaintiffs' Motion for Preliminary Injunction ("Schønau Dec.") ¶ 9. The thickness of the slices is two- to three-times less than the diameter of a typical cell nucleus. Declaration of Robert Singer in Support of Defendant's Opposition to Plaintiffs' Motion for Preliminary Injunction ("Singer Dec.") ¶ 10. As a result, most of the nuclei in a histologic tissue sample will be partial slices of a complete nucleus. Id. During the majority of a cell's life cycle—"interphase," or the period between cell divisions—the cell's DNA is distributed throughout the nucleus. Thus, a given slice of nucleus will not reliably contain all of the cell's DNA. Id.

LEGAL STANDARD

"A preliminary injunction is a provisional remedy, the purpose of which is to preserve status quo and to prevent irreparable loss of rights prior to final disposition of the litigation." Napa Valley Publ'g Co. v. City of Calistoga, 225 F. Supp. 2d 1176, 1180 (N.D. Cal. 2002) (Chen, Mag. J.) (citing Sierra On Line, Inc. v. Phoenix Software, Inc., 739 F.2d 1415, 1422 (9th Cir. 1984)). In light of

these considerations, a plaintiff seeking preliminary injunctive relief must demonstrate either: "(1) a likelihood of success on the merits and the possibility of irreparable injury; or (2) that serious questions going to the merits [have been] raised and the balance of hardships tips sharply in [the plaintiff's] favor." Southwest Voter Registration Educ. Project v. Shelley, 344 F.3d 914, 917 (9th Cir. 2003) (en banc) (per curiam) (citing Clear Channel Outdoor, Inc. v. City of Los Angeles, 340 F.3d 810, 813 (9th Cir. 2003)); see also Sun Microsystems, Inc. v. Microsoft Corp., 188 F.3d 1115, 1119 (9th Cir. 1999). The components of these two tests, together with the added consideration of the public interest, operate on a sliding scale or "continuum." Southwest Voter, 344 F.3d at 918. Consequently, "the less certain the district court is of the likelihood of success on the merits, the more plaintiffs must convince the district court that the public interest and balance of hardships tip in their favor." Id. (citation omitted); see also Miller v. California Pac. Med. Ctr., 19 F.3d 449, 456 (9th Cir. 1994) (en banc).

DISCUSSION

Dako challenges plaintiffs' request for a preliminary injunction on a number of grounds. First, with respect to plaintiffs' chance of prevailing on the merits, Dako offers a number of arguments for why the accused kit does not infringe either asserted patent, and for why the asserted patents are invalid and unenforceable. With respect to irreparable harm, Dako argues that sales of its accused kit are currently minimal, that Dako is capable of satisfying any money judgment, and that plaintiffs' past conduct in prosecuting and then licensing the asserted patents belies any claim of irreparable harm. Dako argues that it will face substantial hardship by being shut out of the market. Finally, Dako argues that public interest favors having multiple kits on the market that assist in the treatment of breast cancer.

Plaintiffs dispute each of Dako's arguments with respect to the likelihood of success on the merits. Plaintiffs also argue that Dako poses a significant threat to Abbott's market share by virtue of Dako's ability to exploit the existing market for its older kit. Abbott claims that it stands to lose a number of multi-year contracts as a result of competition with Dako. Finally, plaintiffs argue that

Dako's entry into the market is particularly unjust given the large amount of time and expense that Abbott has poured into the development and marketing of its own kit.

I. Likelihood of Success

In order to demonstrate a likelihood of success on the merits, plaintiffs must establish that Dako's HER2 kit likely infringes one of the asserted patents, and that Dako's validity and enforceability challenges to the asserted patents are likely to fail. See Oakley, Inc. v. Sunglass Hut Int'l, 316 F.3d 1331, 1339–40 (Fed. Cir. 2003).

A. The '841 Patent

1. Infringement

Determination of infringement is a two-step process. First, the court must determine the meaning of the language of the claims, a question of law. Markman v. Westview Instruments, Inc., 517 U.S. 370, 384 (1996). Second, the finder of fact must compare the construed claims to the accused product, to determine if each claim element is present, either literally or under the doctrine of equivalents. Irdeto Access, Inc. v. Echostart Satellite Corp., 383 F.3d 1295, 1299 (Fed. Cir. 2004).

The '841 patent has only a single independent claim, claim 1, which reads as follows:

> 1. A method of staining target chromosomal DNA comprising:
>
> (a) providing 1) labeled nucleic acid that comprises fragments which are substantially complementary to nucleic acid segments within the chromosomal DNA for which detection is desired, and 2) **blocking nucleic acid** that comprises fragments which are substantially complementary to repetitive segments in the labeled nucleic acid; and
>
> (b) employing said labeled nucleic acid, blocking nucleic acid, and chromosomal DNA in in situ hybridization so that labeled repetitive segments are substantially blocked from binding to the chromosomal DNA, while hybridization of unique segments within the labeled nucleic acid to the chromosomal DNA is allowed, wherein blocking of the labeled repetitive segments is sufficient to permit detection of hybridized labeled nucleic acid containing unique segments, and **wherein the chromosomal DNA is present in a morphologically identifiable chromosome or cell nucleus during the in situ hybridization**.

'841 patent at 17:4–25 (emphasis added). For purposes of opposing the motion for a preliminary injunction, Dako claims that the accused kit does not meet two of the limitations of claim 1. First,

Dako claims that the tissue samples on which the accused kit operates do not contain a "morphologically identifiable" chromosome or cell nucleus because they are made up of slices of cell nuclei containing interphase chromosomal material. Second, Dako argues that the kit does not employ "blocking nucleic acid," but instead uses PNAs, compounds comprising amino acid chains ("peptides") attached to nucleotide bases.

a. "morphologically identifiable chromosome or cell nucleus"

i. Claim Construction

The parties agree that "morphologically identifiable chromosome" refers to a chromosome that has consolidated in metaphase, and not a chromosome that is distributed throughout the nucleus during interphase. The parties also agree that the accused kit does not make use of morphologically identifiable chromosomes. The dispute centers on the meaning of "morphologically identifiable . . . cell nucleus." Dako proposes that "morphologically identifiable . . . cell nucleus" should be construed to mean an "intact" nucleus—one that retains its entire complement of chromosomal DNA. Plaintiffs contend that "morphologically identifiable . . . cell nucleus" should be construed to mean "capable of being identified by its form and structure." Plaintiffs' proposed construction, unlike Dako's, does not require that the nucleus contain the full set of DNA.

In Regents of the University of California v. Oncor, 44 U.S.P.Q.2d 1321 (N.D. Cal. 1997) (Walker, J.), this court already construed the phrase in claim 1 of the '841 patent that is at issue here. The parties in Oncor disputed whether the phrase "a morphologically identifiable chromosome or cell nucleus" referred narrowly to a single target nucleus or chromosome, or more broadly to multiple target nuclei or chromosomes. 44 U.S.P.Q.2d at 1324. UC Regents, the plaintiff in Oncor, argued that the claimed process was limited to operation on a single nucleus because, among other reasons, the principal advantage of the invention was the ability to "detect unique DNA sequences on a single chromosome or cell nucleus." Id. The defendant in Oncor argued that the disputed phrase "merely clarifies that the target chromosomal DNA are present in intact chromosomes or cell nuclei, but does not limit the number of these structures." Id. After a review of the meaning of the word "a," the court reviewed the intrinsic record and concluded that the claim phrase was

ambiguous. In light of the ambiguity, the court construed the phrase narrowly—against the drafter—to refer to a single chromosome or cell nucleus. Id. at 1326.[3]

The doctrine of construing ambiguity "against" the drafter actually benefitted UC Regents considerably, as the court's narrow construction provided the basis for granting summary adjudication that the claimed invention was not anticipated or rendered obvious by prior art. The prior art processes in question, like the process described in the '841 patent, used unlabeled repetitive sequences to prevent labeled probes from binding to the repetitive sites on the target chromosomes. Id. at 1327. The prior art process, however, relied upon "frequency distribution tables revealing the sites where the hybridizations were most likely to occur" because the binding was not reliable enough to permit detection in a single cell. Id. As the prior art process did not "permit detection of target chromosomal DNA on a single chromosome or cell nucleus" as required by the court's construction of the claim language, the court concluded as a matter of law that the cited prior art did not invalidate the patent under 35 U.S.C. sections 102 or 103. Id. at 1328.

Plaintiffs claim not to contest the court's construction in Oncor, but argue that the "single cell nucleus" required by the '841 patent need not be completely intact.[4] In support of their argument, plaintiffs rely on a portion of the specification, which states that optimum practice of the invention requires preparing the nucleus in a way that promotes easy hybridization, but "does not cause unacceptable loss of morphological detail." '841 patent at 11:66–67. According to plaintiffs, this language suggests that the nucleus need not be completely intact, but must only retain enough of its structure to remain recognizable. However, the portion of the specification cited by plaintiffs is not helpful in resolving the issue in this case, which is whether the nucleus must retain its full set of genetic material.

The court's ruling in Oncor, on closer inspection, strongly favors Dako's proposed construction. According to the Oncor court, the claimed process must be able to "[detect] hybridized labeled nucleic acid containing unique segments" in a single "morphologically identifiable . . . cell nucleus." Id. at 17:20–22. For the claimed process to operate successfully on a single nucleus, that single nucleus must, at a minimum, contain the full set of chromosomal DNA. If the single cell does not contain the full set of DNA, there is some chance that the portion of the

DNA containing the target region is not present. A failure to detect the target in a single incomplete set of DNA is therefore inconclusive.

Thus, combining the court's express construction of the overall claim phrase in Oncor with the implicit additional requirement that the cell nucleus contain the full complement of chromosomal DNA, the court construes the phrase "morphologically identifiable . . .cell nucleus" to refer to a single cell nucleus that contains the full complement of chromosomal DNA.

ii. Application to the Accused Kit

In light of the requirement that the target nucleus contain the full complement of chromosomal DNA, it appears that plaintiffs will have great difficulty proving literal infringement. In Dako's accused process, the target nuclei are presumed *not* to have a complete complement of DNA. The Dako HER2 kit relies on two additional pieces of information to compensate for the loss of chromosomal material in each sliced nucleus. First, the accused kit relies on counting target regions across multiple partial nuclei. Schønau Dec. ¶ 8. Second, the accused kit uses a second labeled probe, which bonds to exactly one location per full set of chromosomal material, to provide a count of how many complete sets of chromosomes are present in the tissue sample. Id. Dividing the total number of locations of the HER2 gene by the total number of complete sets of chromosomes present yields the number of HER2 genes per cell, which is the desired result. Id.

The accused process is thus probabilistic; it depends on the aggregation of data from multiple nuclei in order to yield an accurate count of the HER2 gene, and cannot reliably be performed on a single formalin-fixed nucleus slice. In this respect, the accused process is similar to the prior art that UC Regents expressly disclaimed in Oncor in order to preserve the validity of the '841 patent. Indeed, the argument advanced by plaintiffs is strikingly similar to the argument UC Regents successfully opposed in Oncor. Plaintiffs in this case make the following argument:

> During prosecution, when the "morphologically identifiable" limitation was added to the claims, The Regents' counsel specifically pointed to the specification's explanation that, with respect to the chromosomal DNA, it is important "not [to] cause unacceptable loss of morphological detail." . . . The amendment was made in response to the Examiner's concern that the term "chromosomal DNA" described only the source of the target DNA, but not the *form* of the DNA. . . . In response, the applicants explained that the chromosomal DNA is to be used in *in situ* hybridization

> and must therefore be in "some natural biological structure" although that structure "*may be partially dismantled to allow good hybridization.*"

Pls.' Reply Brief at 7 (emphasis in original). Similarly, in Oncor the defendant argued that the phrase "morphologically identifiable" clarified "that the target chromosomal DNA are present in intact . . . cell nuclei"—i.e., "some natural biological structure." Oncor, 44 U.S.P.Q.2d at 1324. In support of this argument, Oncor also cited the prosecution history:

> Oncor argues that several exchanges in the prosecution history suggest that the last phrase of step (b) was added to clarify the *form* of the target DNA, rather than their [sic] number. This evidence consists, in part, of statements by the applicant that the amended language was added to address the examiner's concern that the chromosomal DNA could have been processed prior to hybridization . . . and makes clear that the chromosomal DNA retain their morphological detail.

Id. at 1325 (emphasis added). Oncor, like plaintiffs in this case, argued in essence that the "morphologically identifiable . . . cell nucleus" limitation required only that the nucleus retain some of its shape. As already noted, the Oncor court rejected this argument at the urging of UC Regents and on that basis granted summary adjudication of validity over the prior art.

The court acknowledges that the source of uncertainty in the prior art—the lack of reliable binding to only the unique regions—is different from the source of uncertainty in the accused kits, which flows from the lack of a full set of chromosomes in any given cell nucleus slice. What UC Regents disclaimed in order to prevail in Oncor, however, is broad: processes that require hybridization in multiple nuclei. UC Regents might have argued Oncor differently in light of the Dako kit, and plaintiffs may still find some valid basis for distinguishing Oncor in this case. The court need not reach the ultimate question of whether plaintiffs will succeed in doing so; it is enough to say that the reasoning of the Oncor court raises serious questions with respect to plaintiffs' infringement argument in this case.

Plaintiffs argue that the'841 patent expressly contemplates hybridization in "fixed" tissue samples such as those used in the accused kit. The '841 patent does state that as part of the processing prior to hybridization the cells may be "fixed," or hardened, through the application of chemicals such as "acid alcohol solutions," "acid acetone solutions," or "various aldehydes such as formaldehyde . . . ." Id. at 11:40–42. The '841 patent also states that the chromosomes may be "treated with agents to remove proteins" prior to hybridization. Id. at 11:60–61. Defendant

acknowledges that the accused kit also employs a hardening agent—formalin—and deproteinization prior to hybridization. The problem with plaintiffs' infringement position is not that the accused kit uses fixatives, however, but that the accused kit operates on partial nuclei. The fact that the patent contemplates the use of fixatives is therefore irrelevant.

Plaintiffs also argue that even if the tissue samples on which Dako's kit operates do not generally contain entire nuclei, even a single intact nucleus is all that is required for infringement. If this intact nucleus could be identified and distinguished from the various partial nuclei, plaintiffs' argument might have merit. Plaintiffs have presented no evidence, however, that it is possible to determine by looking at the histologic sample which of the nuclei is intact, such that someone using Dako's kit could reliably detect the target region in a single cell nucleus.

Plaintiffs may be able to make some additional infringement argument that is not yet before the court. On the basis of the current record, however, the court finds that plaintiffs have not succeeded in establishing a likelihood of success on the merits with respect to infringement of the "morphologically identifiable chromosome or cell nucleus" element.

b. "blocking nucleic acid"

Each claim of the '841 patent further requires that the process employ "blocking nucleic acid" to reduce binding to repetitive sections. Plaintiffs acknowledge that the accused kit does not literally contain "blocking nucleic acid," but contend that PNA is equivalent to nucleic acid. As Dako notes, determination of infringement under the Doctrine of Equivalents is a "highly factual inquiry" which "rarely comes clear on a premature record." Jeneric/Pentron, Inc. v. Dillon Co., 205 F.3d 1377, 1384 (Fed. Cir. 2000). Dako has submitted expert testimony in connection with its brief in opposition that PNA probes accomplish blocking in a substantially different way from DNA probes and are not "interchangeable" with DNA. For example, PNA probes can bind to DNA that has not been denatured. Declaration of James Coull in Support of Defendant's Opposition to Plaintiff's Motion for Preliminary Injunction ("Coull Dec.") ¶¶ 23–26. PNA is also less susceptible to changes in hybridization conditions, such as temperature. Id. The court is reluctant to make a

factual finding as to infringement under the Doctrine of Equivalents, faced with conflicting credible testimony, in the context of a motion for a preliminary injunction.

The court therefore finds that plaintiffs have not succeeded in establishing a likelihood of success on the merits with respect to infringement of the "blocking nucleic acid" element.

2. Validity and Enforceability

Dako notes that the Oncor court denied summary judgment as to two challenges to the validity and enforceability of the '841 patent. This court need not consider the ultimate merits of either challenge in order to resolve plaintiffs' motion for a preliminary injunction, but finds that the presence of fact issues as to validity and enforceability which could not be resolved on summary judgment further diminishes plaintiffs' likelihood of success. See, e.g., Oakley, 316 F.3d at 1339–40 (holding that an "injunction should not issue if the party opposing the injunction raises 'a substantial question concerning infringement or validity, meaning that it asserts a defense that [the party seeking the injunction] cannot prove lacks substantial merit.'") (citing Tate Access Floors, Inc. v. Interface Architectural Resources, Inc., 279 F.3d 1357, 1365 (Fed.Cir.2002)).

B. The '479 Patent

1. Infringement

The '479 patent contains the same"morphologically identifiable chromosome or cell nucleus" claim limitation that the court has already evaluated in the context of the '841 patent. For the reasons already stated, the court finds that plaintiffs have not succeeded in establishing a likelihood of success on the merits with respect to infringement of the "morphologically identifiable chromosome or cell nucleus" element.

The claims of the '479 patent have a further problem vis-á-vis the accused kit in that they are limited to the use of "a heterogeneous mixture of labeled unique sequence nucleic acid fragments." '479 patent at 16:9–10. Dako argues that this limitation excludes processes which employ probes corresponding to repetitive sequences. Plaintiffs argue that the phrase should be construed to mean "a heterogeneous mixture of labeled nucleic acid fragments that includes unique sequences," but

may also contain repetitive sequences.

Plaintiffs' proposed construction is difficult to accept in light of the claims of the '841 patent, which is prior art to the '479 patent under 35 U.S.C. section 102(b). Claim 1 of the '479 patent explains that the "unique sequence nucleic acid fragments" are "substantially complementary to nucleic acid segments within the interphase chromosomal DNA *for which detection is desired.*" Id. at 16:10–13 (emphasis added). Likewise, the claims of the '841 patent require the use of "labeled nucleic acid that comprises fragments which are substantially complementary to nucleic acid segments within the chromosomal DNA *for which detection is desired*"—the very same phrase used in the '479 patent. '841 patent at 17:6–12 (emphasis added). Claim 1 of the '841 patent further requires "blocking nucleic acid that comprises fragments which are substantially complementary to repetitive segments in the labeled nucleic acid." Id. Plaintiffs' proposed construction suggests that the '479 patent, like the '841 patent, contemplates the use of both unique and repetitive probes. If this is true, plaintiffs' proposed construction appears to eliminate much of the difference between the inventions claimed in the two patents.

It is not disputed that the accused kit makes use of probes having both unique and repetitive sequences. The court therefore has serious concerns about plaintiffs' ability to simultaneously preserve validity and establish infringement with respect to the claims of the '479 patent.

For both of the reasons just discussed, the court finds that plaintiffs have not shown a likelihood of success in proving infringement of any valid claim of the '479 patent.

2. Validity and Enforceability

The validity and enforceability challenges discussed in Oncor also apply to the '479 patent, which contains the same specification as the '841 patent. For the reasons discussed above, the presence of substantial validity and enforceability questions further weighs against the grant of an injunction.

II. Balance of Hardships

Having concluded that plaintiffs have not shown a likelihood of success on the merits, the court now turns to whether they have shown that the balance of hardships tips sharply in their favor.

Plaintiffs argue that permitting Dako to continue selling the accused kit will irreparably harm Abbott for three reasons. First, plaintiffs contend that Dako is using its existing customer base as leverage in promoting sales of the accused kit, which Dako is allegedly "bundling" with the older kit at a substantially discounted price. Plaintiffs argue that Dako's discounted pricing will force Abbott to reduce the price of its competing PathVysion kit. Second, plaintiffs contend that Dako's marketing of its accused kit as a "companion" to the older, protein-based test undermines Abbott's attempts to make its genomic PathVysion test the primary tool for detecting excess HER2 genes. Third, plaintiffs argue that Dako's participation in the market for genomic tests erodes Abbott's position as a market leader.

Dako, in response, argues that its current market share of genomic tests is minimal and that it will likely be able to satisfy any money judgment against it. Plaintiffs counter that the ability to satisfy a money judgment is not sufficient to overcome the presumption of irreparable harm that attaches in patent lawsuits. See, e.g., Polymer Techs., Inc. v. Bridwell, 103 F.3d 970, 975–76 (Fed. Cir. 1996); Purdue Pharma L.P. v. Boehringer Ingelheim GMBH, 237 F.3d 1359, 1368 (Fed. Cir. 2001). As Dako correctly points out, a presumption of irreparable harm only attaches when the patent holder establishes a likelihood of success on the merits. See id. at 1367 ("Purdue made a clear showing of its likely success on the merits. Therefore, under the rule prevailing in our circuit, Purdue was entitled to a rebuttable presumption of irreparable harm."); Reiffin v. Microsoft Corp., 158 F. Supp. 2d 1016, 1028 (N.D. Cal. 2001) (Walker, J.). Here, as already discussed, plaintiffs have not shown a likelihood of success on the merits. Thus no presumption of irreparable harm applies.

Unconstrained by any presumption, the court finds that plaintiffs' alleged harms can be addressed in the calculation of damages should they prevail in establishing infringement and should Dako's validity and enforceability challenges fail. See Nutrition 21 v. United States, 930 F.2d 867, 871 (Fed. Cir. 1991) ("neither the difficulty of calculating losses in market share, nor speculation

that such losses might occur, amount to proof of special circumstances justifying the extraordinary relief of an injunction prior to trial."). The balance of hardships therefore do not tip sharply in plaintiffs' favor.

In sum, plaintiffs' have failed to show either a likelihood of success on the merits or a favorable balance of hardships. Preliminary injunctive relief is therefore inappropriate.

CONCLUSION

For the above reasons the court hereby DENIES plaintiffs' motion for a preliminary injunction.

IT IS SO ORDERED.

Date: March 10, 2006

MARILYN HALL PATEL
United States District Judge
Northern District of California

ENDNOTES

1. Unless otherwise noted, background facts are taken from the declarations submitted with the parties' briefs, and are not in dispute.

2. Although the parties did not brief the issue in connection with the instant motion, it appears that the '841 patent is limited to the use of blocking DNA which is complementary to labeled probes containing repeat sequences, as opposed to the repeat sequences on the chromosomal DNA itself.

3. Dako also points to language earlier in the Oncor opinion, which explains the invention: "[t]his process is known as in situ hybridization when it occurs on intact, or morphologically identifiable, chromosomes or cell nuclei." Id. at 1323. As plaintiffs point out, the quoted passage is not part of the court's claim construction. The quoted language suggests, at most, that the Oncor court assumed that "morphologically identifiable" meant "intact," without expressly so deciding.

4. Nor could plaintiffs reasonably do so. Regardless of general concerns of uniformity in construction of the same claim terms in different lawsuits, see Markman, 517 U.S. at 391, plaintiffs would likely be judicially estopped from advocating a different construction in this case. The Oncor court accepted UC Regents' construction, and the narrow construction was necessary to the court's grant of summary adjudication of lack of anticipation and obviousness. See generally New Hampshire v. Maine, 532 U.S. 742, 750 (2001).